REMARKS

I. Sequence compliance

In the Office action mailed on March 26, 2004, the Examiner asserted that the specification is missing a sequence listing which includes amino acid sequence presented on page 29 of the application as filed. In response, Applicants respectfully submit that a sequence listing including the aforementioned sequence was in fact filed in Applicant's Response to Office Communication on January 27, 2004. Specifically, Applicants point to page 3 of the Response, and pages 9-11 of the substitute sequence listing filed therewith.

The Examiner further asserted that the sequence on page 59 is improperly identified. However, upon review of page 59 of the specification as filed, Applicants are unable to identify the recitation of an amino acid sequence. If the Examiner intended to recite page 60 rather than page 59, then Applicants respectfully point out that page 60 was also amended in Applicant's Response to Office Communication on January 27, 2004. Specifically, Applicants point to page 3-4 of the Response, and page 10 of the substitute sequence listing filed therewith. Applicants therefore respectfully request clarification from the Examiner.

II. Status of the Claims

Claims 33-40 are pending in this application. Claims 33-40 are rejected under 35 USC §112, first and second paragraphs.

III. Declaration pursuant to 37 CFR §1.63

In the Office action, the Examiner asserted that the Declaration filed February 4, 2002, is a copy of the Declaration filed in U.S. Application No. 08/477,648, while the instant application appears to be a divisional application of U.S. Application No. 09/640,737. In response, Applicants confirm that the instant application is a divisional of U.S. Application Nos. 09/640,737 and 08/477,648 and are related to U.S. Application No. 08/244,603. Accordingly, the Declaration submitted on February 4, 2002 is correct.

IV. Drawings

In the Office action the Examiner asserted that the figures of the instant application are presented on separate pages or in separate panels. In response, Applicants file herewith a corrected set of figures. Applicants further submit that the amendments to the

specification, identified above, merely reflect the requisite amendments as a result of the new set of figures.

V. Abstract of the invention

The Examiner reminded the Applicants of the proper language and format for an abstract of the disclosure in the Office action. In response, Applicants file herewith a substitute abstract as indicated above in the amendments to the specification.

VI. The rejection under 35 USC §112, first paragraph, must be withdrawn

The Examiner rejected claims 33-40 under 35 USC §112, first paragraph, for assertedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make the invention. Specifically, the Examiner asserted the instant specification fails to provide guidance as to how to make the claimed antibody, thereby requiring undue experimentation to discover how to use Applicant's invention. The Examiner further asserts that the instant specification as filed fails to present any guidance on how to produce an antibody that binds to phosphorylated Serine at position 262 and does not bind native or dephosphorylated Serine at residue 262. The Applicants respectfully traverse.

First, the Applicants submit that skill level in the field of the invention is high. In fact, the Examiner readily admits that "[w]hile the skill level in the art is high, the level of predictability is low" (See Office action at page 7). The proper grounds for a rejection based on asserted lack of enablement is found in *Hybritech v. Monoclonal Antibodies*, 231 USPQ 81 (Fed. Cir. 1986) wherein the Court stated that "a patent need not teach, and preferably omits, what is well known in the art" (*Id.* at 94) and temporally, this determination is made at the filing date of the application. *Id.* Procedures for making and identifying antibodies are well known in the art (See, e.g., *Antibodies: A Laboratory Manual*, Harlow and Lane (eds.), Cold Spring Harbor Laboratory Press, 1988). Considering the above admission and skill level, Applicants submit that undue experimentation would not be required to use Applicant's invention as presently claimed. Accordingly, the rejection under 35 USC §112, first paragraph, must be withdrawn.

VII. The rejection under 35 USC §112, second paragraph, must be withdrawn

Claims 33 and 39 were rejected under 35 USC §112, second paragraph, for assertedly being vague and indefinite insofar as they employ the term "tau" as a limitation, followed by a refernce to a residue located within SEQ ID NO: 1 without disclosing a connection between "tau" and the amino acid sequence. As suggested by the Examiner, the Applicant's have amended claims 33 and 39 to identify "tau" by a SEQ ID NO. Accordingly, the rejection under 35 USC §112, second paragraph, must be withdrawn.

Claims 39 and 40 were rejected under 35 USC §112, second paragraph, for asserted lack of antecedent basis for the phrase "phosphorylated residue-binding antibody." In response, the Applicants have amended claim 39 to replace the phrase "a phosphorylated residue-binding antibody of" with the phrase "an antibody that binds phosphorylated tau according to." Accordingly, the rejection under 35 USC §112, second paragraph, must be withdrawn.

Finally, the Examiner rejected claims 34-38 for being dependent from an indefinite claim. The Applicants submit that the amendments and comments above render this rejection moot. Accordingly, the rejection under 35 USC §112, second paragraph, must be withdrawn.

VIII. The double patenting rejection must be withdrawn

The Examiner advised the Applicants that claims 34-35, as well as claim 40 will be objected to under 37 CFR 1.75 as being a substantial duplicate of claim 33 and claim 39, respectively. The Applicants respectfully request that the double patenting rejection be held in abeyance until allowance of claimed subject mater has been acknowledged.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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